RVD2008-30

Re-evaluation Decision

Chlorthal

(publié aussi en français)

14 August 2008

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6605C
Ottawa, Ontario
K1A 0K9

Internet: pmra_publications@hc-sc.gc.ca
www.pmra-arla.gc.ca
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra_infoserv@hc-sc.gc.ca

Canada

ISBN: 978-0-662-48820-0 (978-1-100-10451-5)
Catalogue number: H113-28/2008-30E (H113-28/2008-30E-PDF) .

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Overview

Re-evaluation Decision

After re-evaluating the herbicide chlorthal, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing chlorthal for sale and use in Canada.

An evaluation of available scientific information found that products containing chlorthal do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of chlorthal use, new risk-reduction measures must be included on the labels of all products. Additional data are being requested as a result of this re-evaluation.

The regulatory approach for the re-evaluation of chlorthal was first presented in Proposed Re-evaluation Decision PRVD2008-18, *Chlorthal*, a Consultation Document.[1] This Re-evaluation Decision[2] describes PMRA's regulatory process for re-evaluating chlorthal as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2008-18. To comply with this decision, registrants of products containing chlorthal will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers the potential risks and value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Chlorthal, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of chlorthal. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy).

The USEPA re-evaluated chlorthal and published its conclusions in a 1998 RED.

For more details on the information presented in this PMRA re-evaluation decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2008-18, *Chlorthal*.

What Is Chlorthal

Chlorthal is a herbicide used to control weeds in agricultural crops, turf and ornamentals. It is applied by farm workers or professional applicators using ground equipment.

Health Considerations

Can Approved Uses of Chlorthal Affect Human Health?

Chlorthal is unlikely to affect your health when used according to the revised label directions.

People could be exposed to chlorthal through consumption of food and water, working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that chlorthal was unlikely to affect human health provided that the new risk-reduction measures were implemented. These conclusions also apply to Canada and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes by evaluating scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Chlorthal is currently registered in Canada for use on several food commodities and the following MRLs have been established:

- 5 ppm on mustard greens and turnip greens;
- 2 ppm on beans, black-eyed peas, collards, kale, lettuce, peppers, pimentos, potatoes, soybeans, strawberries, sweet potatoes, turnips and yams; and
- 1 ppm on broccoli, Brussels sprouts, cabbage, cantaloupes, cauliflower, cucumbers, eggplants, garlic, honeydew melons, onions, summer squash, tomatoes, watermelons and winter squash.

Chlorthal could also be used in other countries on crops that are imported into Canada. Where no specific MRL has been established a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Chlorthal Is Introduced Into the Environment?

Chlorthal is unlikely to affect non-target organisms when used according to the revised label directions.

Non-target species (birds, mammals, bees, aquatic organisms and terrestrial plants) could be exposed to chlorthal in the environment. Environmental risks such as this are assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are then compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the re-registration of chlorthal was acceptable provided risk-reduction measures to further protect the environment were implemented. These conclusions apply to Canada and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of chlorthal, the PMRA is requiring further risk-reduction measures for the product label.

Human Health

- Reduction of the maximum application rate on vegetables and a requirement for additional protective equipment to protect mixers/loaders/applicators
- A restricted-entry interval following application on agricultural crops, ornamentals, sod farms to protect mixers/loaders/applicators
- A water-in requirement following application to turf to protect mixers/loaders/applicators.

Environment

- Reduction of the maximum application rate on vegetables to protect non-target organisms
- Additional advisory label statements to reduce potential surface and groundwater contamination to protect non-target organisms.

In addition to the above, the registrant has volunteered to cancel residential uses, late fall application on turf and use on beans, potatoes and peas.

Other Information

Anyone may file a notice of objection[3] regarding this decision on chlorthal within 60 days from the date of publication of this Re-evaluation Decision.

For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Request a Reconsideration of Decision, www.pmra arla.gc.ca/english/pubreg/reconsideration-e.html), or contact the PMRA's Pest Management Information Service by phone (1-800-267-3615) or by e-mail (pmra_infoserv@hc-sc.gc.ca)

[3] As per subsection 35(1) of the *Pest Control Products Act*.